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Award Number: W81XWH-08-2-0066

TITLE: "Addressing the Needs of Children and Families of Combat Injured "

PRINCIPAL INVESTIGATOR: Stephen J. Cozza, M.D.

CONTRACTING ORGANIZATION: The Henry Jackson Foundation
Bethesda, MD 20817

REPORT DATE: April 2013

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
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1. REPORT DATE April 2013		2. REPORT TYPE Annual		3. DATES COVERED 31 March 2012 to 30 March 2013	
4. TITLE AND SUBTITLE "Addressing the Needs of Children and Families of Combat Injured"				5a. CONTRACT NUMBER W81XWH-08-2-0066	
				5b. GRANT NUMBER W81XWH-08-2-0066	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Stephen J. Cozza, M.D. E-Mail: stephen.cozza@usuhs.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) The Center for the Study of Traumatic Stress Uniformed Services University 4301 Jones Bridge Rd Bethesda, MD 20814				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Enrollment closed at 2 sites. We have a total of 116 families (223 participants). Approximately 50% of participants are halfway complete with the study (6-mo follow-up) and 25% have completed (12mo follow-up). We continue data collection. We continue data entry and initial data analysis.					
15. SUBJECT TERMS Combat injury, families, children, service members, distress, injury communication, parenting, assessment, adjustment					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

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INTRODUCTION:

This investigation focuses on measuring the impact of parental combat injury on military children and families. The study is a longitudinal design comparing families of combat-injured service members (CI group) and non-injured service members (NI group) across a 12-month time-frame. The CI group will be comprised of 200 injured service members and their spouses with at least one child under the age of 18-years-old recruited from Walter Reed National Military Medical Center (WRNMMC) and San Antonio Military Medical Center (SAMMC) within the first two years of initial hospitalization. The NI group will be comprised of 200 active duty non-injured combat veterans (matched with CI participants for combat experience and relevant demographic factors) and their spouses with at least one child under the age of 18-years-old recruited from Ft. Stewart, GA (FSGA), within two years of returning from deployment. Families will be assessed using self-report questionnaires and, for the CI Group, record review of a semi-structured interview currently used at clinical sites. Consenting parents and assenting children ages 6 to 17 years will complete questionnaires assessing the following domains: parental trauma exposure history, symptoms, and function; child traumatic exposure history, symptoms and function; parenting behaviors; and family functioning. Follow-up assessments of parental symptoms and functioning, child symptoms and functioning, parenting behaviors, and family functioning will be completed 6 and 12 months after the initial assessment. For families who are not available to complete in-person assessment at 6 and/or 12 months, assessment will be conducted by telephone and measures will be administered verbally or assessment will be conducted online. Families will also be briefly contacted at 3-months and 9-months after baseline to check-in and inquire whether they are in need of additional resources.

BODY:

Below is a summary of the major activities undertaken by project team members during the last 12 months organized by the timeline in the Schedule of Work (SOW):

1. **Staff/Clinician Hiring and Training:** In Progress.

WRNMMC: Research Clinicians (RCs) fully trained and in the field collecting data.

SAMMC: Two full-time RCs were in the field. However, one of the two full-time staff recently resigned from the position. The CSTS staff and a consultant are providing remote support by conducting the follow-up data collection interviews.

FSGA: One full-time RC is trained and in the field recruiting and collecting data. We have also recently hired a 2nd full-time RC. She will begin April 22, 2013.

2. **Site approval and planning:** Complete.

All IRB and HRPO approvals are in place at all sites.

3. **Organization and Preparation:** Complete.

Organizational Systems. Across all sites, we continued the implementation of the study organization systems for recruitment, enrollment, data collection, and monitoring. Tracking is conducted with encrypted documents via secure DoD system.

Recruitment Materials and Strategies. Across all sites, we continued recruitment efforts to generate provider and self-referrals. These included flyers, posters, information tables, and presentations to community and clinical providers. We also instituted a “screener” for providers to use while families are checking in. It consists of 3 questions to broadly determine eligibility and interest: 1) has service member been injured (or returned from deployment in the past 2 years), 2) does family have child under 18 years, and 3) are they interested in receiving more information about the study. Both community and clinical providers have positively responded to using the screener because it minimizes their burden for referral to the study. At the same time, it gives us a wide reach to the population and narrows efforts to those families who are potentially eligible for the study.

At WRNMMC, we recruited from: Patient Consultant Liaison Services (inpatient), Psychiatry (inpatient)-Operation Brave Families, Occupational Therapy for amputees, Warrior Clinic (outpatient), Warrior Transition

Battalion, Community fairs (Health Fair, Spring Fling, Fall Festival, Resource Fair), previous study contact, Support group (Family Care Club)

At SAMMC, we recruited from: Center for the Intrepid (outpatient), Pediatric Outpatient Clinic, FSH Outpatient Adolescent Clinic, Warrior and Family Support Center, Warrior Transition Unit/Battalion (Social Work, Command), Soldier & Family Assistance Center, Army Wounded Warrior Program, Operation Homefront, MCEC School Liaison at Ft Sam Houston, Behavioral Health, Occupational Therapy, Community fairs (Caregiver conference, Family Day)

At FSGA, we recruited from: CYSS, Commissary, Px, Hawks Medical Clinic, Community fairs (Spring Education Forum, Wheels Day, Back to School Fair), Winn Army Community Hospital, OB/GYN, CLIF, Pediatrics, Behavioral Health, Deployment Fairs, CDC, Family Practice, Americorps

4. Finalize Plans: Complete.

All sites are coordinated enrollment and data collection. We continue to maintain and build relationships on site for office space and space with families.

5. Participant Enrollment: In Process.

Year 5 Enrollment Totals by Site				
	Families	Adults	Spouse/SM	Children
WRNMMC	27	50	27/23	16
SAMMC	10	14	10/4	13
FSGA	37	41	37/4	10
		105 Adults	74/31 SP/SM	39 Children
TOTAL	74 Families	144 participants		

Through Mar31, 2013

Cumulative Study Enrollment Totals by Site				
	Families	Adults	Spouse/SM	Children
WRNMMC	52	94	49/45	27
		121 participants		
SAMMC	15	21	15/6	17
		38 participants		
FSGA	49	53	49/4	11
		64 participants		
		168 Adults	113/55 SP/SM	55 Children
TOTAL	116 Families	223 Participants		

Through Mar31, 2013

We closed enrollment at the hospital sites in January 2013, but continue enrollment at the non-injury site, Ft. Stewart, through non-CDMRP CSTS funding. In year 5, we enrolled a total of 74 families; cumulatively since the launch of the study, we have enrolled 116 families.

WRNMMC: In year 5, we enrolled 27 families, nearly all including both Spouse and Service Member. Enrollment has closed at WRNMMC and we enrolled a total of 52 families.

SAMMC: In year 5, we enrolled 10 families. It was more difficult to recruit the SM for participation. Several indicated that they were already participating in other research studies and did not want to add another one. Enrollment closed at SAMMC and we enrolled a total of 15 families.

FSGA: In year 5, we enrolled 37 families. It was more difficult to recruit the SM for participation because of their fears of research negatively impacting career. Spouses are also reluctant to allow children to participant. Overall, we find that these active duty families are wary of research investigating family life and, without tangible/monetary incentives for participation, it is even more challenging to recruit participants.

6. Continued Data Collection: In Process

Study Total Completed Follow-up Interviews by Site				
	Baseline Interviews	6-month Interviews	12-month Interviews	Withdrew
WRNMMC	121	87	48	9
SAMMC	38	7	1	2
FSGA	64	25	2	6
TOTAL	223	119	51	17

Through Mar31, 2013

Data collection continues. We continue to follow-up with participants 6- and 12-months after the baseline for additional interviews. Also, we contact participants at 3- and 9-months to check in on family needs and update contact information to minimize attrition. We currently have an overall 7% attrition rate. Those who have withdrawn from the study have study stated that they are too busy or overwhelmed to continue participation.

Approximately 50% of participants are half-way through the study having completed the 6-month interview. Roughly 25% have completed the study. There are participants who we were not able to obtain interviews despite repeated attempts offering in-person, phone, and online options.

7. Monitor Data Collection: In Process.

We continue to maintain connection to RCs through weekly team calls with the project coordinator and RAs. In addition to individual site problem-solving and data collection case management, the call facilitates team building. We also continue to have cross-site monthly project calls with the research team: all site PIs, RCs, project coordinator, and project PI. We work to maximize complete data collection, maintain quality data, and minimize attrition.

We have launched and fully using the online data collection system, PsychData. This has been a helpful tool for the follow-up interviews as several families have moved the original recruitment site (due to hospital transfer or PCS) or have busy schedules making an online, self-administration option preferable. However, we have found that due to families' numerous competing demands- both injured and non-injured- we must prompt participants several times in order to complete.

8. Data Preparation: In Process.

We are preparing the dataset and codebook, beginning with the baseline set. We began and continue data entry of the questionnaires. We continue to clean the data and begin scoring to initiate analyses.

9. Problem Areas:

First, an RC at SAMMC violated the project protocol for questionnaire administration. Three questionnaires were sent home with participants for completion; protocol states questionnaires are completed in-person, by phone or

online. The site PI informed the project PI of the incident and the RC was immediately suspended from all project activities. Project staff secured all project materials. Subsequently, the RC resigned from the position. These violations were reported to the USUHS IRB, as required.

Second, as mentioned above, one of two RCs at SAMMC resigned from the study. This delayed follow-up data collection as we transferred project files and coordinated tasks with the other active CDMRP research project on site. To assist with data collection, core staff at CSTS are providing remote support to the remaining SAMMC RC by collecting interviews via phone and online. Additional tasks to core staff have in turn delayed planned progress on data preparation and entry tasks. We are working to complete interviews quickly.

KEY RESEARCH ACCOMPLISHMENTS:

Enrollment is closed at the hospital sites, ending the recruitment of the combat injured families, but we continue to enroll non-injured families using non-CDMRP/CSTS funding. Compared to the cumulative total last year, we more than doubled our enrollment this year; we currently have 116 families (67 injured and 49 non-injured). Additionally, follow-up data collection continues to be successful with only a 7% attrition rate. One quarter of participants have already completed the study. We are moving into the data entry and analysis phase of the study.

REPORTABLE OUTCOMES:

Early reports (N=29) from combat injured spouses showed that spouses and combat injured service member average age was 30 years with range from 21-45. All couples were married with an average of 7 years. 72% indicated multiple injuries during the focal incident with 51% listing amputation and 48% listing Traumatic Brain Injury as combat injuries. At the time of the baseline interview, 68% of service members were still in the hospital and 82% were active duty. Overall, spouses' current mental health was favorable. None reached clinical thresholds for depression on the Brief Symptom Inventory and less than 5% for anxiety. Seven percent met DSM criterion cut-offs for PTSD on the Post traumatic symptom checklist, which is elevated from prevalence in community samples. Anecdotally, spouses are very overwhelmed with the many needs in their family, however, it is not reflected at clinical levels with validated measures perhaps emphasizing the imperative for empirical research. We are eager to examine the full sample and see how their well-being changes over time, particularly in comparison to the non-injured spouses. (Anecdotally, the non-injured sample has been challenging to engage because spouses are distressed with deployment-related needs and "normative" household tasks.)

Spouses described that 65% of their children had visited their injured parent in the hospital. Families employed various caregiving arrangements for their children. 34% spouses remained primary caregivers, but 32% families grandparents and 21% other relatives were primary caregivers. Simultaneously, living arrangements for children varied. 25% of children lived at home, 42% lived at or near the hospital, and 10% lived at another's home. We see that within the first two since the injury occurred the majority of children see their parent, but multiple transitions in caregiving and homestead are made. We are continuing data analysis to examine these patterns and the impact of transitions on children's functioning.

CONCLUSION:

With a near complete sample, we are urgently collecting follow-up data to maximize study success. We continue with data entry and are moving forward with preliminary analyses of baseline data and will continue with longitudinal effects. Families encounter challenges from baseline to one year, but the empirical nature of families' functioning remains to answered.

REFERENCES:

No references were cited in this annual report.

APPENDICES:

None supplied.